REMARKS

Applicant wishes to thank the Examiner for the courtesy extended to the Applicant representatives Daniel Altman and Daniel Hart and to one of the inventors, Nathalie Zammatteo, by granting a personal interview. As a result of an agreement that was reached at the Interview on June 14, 2006, Claims 45, 52-55, 57-59, 65-68, 70-74, 76, 77 and 79-81 have been amended. Support for the amendments can be found in the claims and the Specification as filed, for example, in Figures 4 and 5, page 9, lines 28-29, page 19, lines 22-24, and page 40, lines 24-26. Claim 51 has been cancelled as redundant. New Claim 89 has been added. Support for the new claim can be found in the Specification as filed, on page 28, lines 20-31. The withdrawn Claim 1 has been amended to depend on Claim 45. It is Applicant's understanding that upon allowance of a product claim, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.04 and fully examined for patentability in accordance with 37 CFR 1.104.

No new matter has been introduced by these amendments. The following addresses the Substance of the Office Action.

Written Description

The Examiner has rejected Claims 45-88 under 35 USC §112, first paragraph as failing to comply with written description requirement. Specifically, the Examiner stated that the target molecules recited in the Claim 45 are described in terms of their function without any associated structural, or physical identifiers. The Examiner also stated that none of the "capture molecules" are impervious to any and all forms of cleavage. The Applicant has amended Claim 45 to recite that capture molecules doe not comprise a cleavable spacer, and that both capture and target molecules are nucleic acids, and reserves the right to pursue the deleted subject matter in a divisional application. Claim 45 was additionally amended to not recite the specific groups of the nucleic acid capture and target molecules. The methodology disclosed in the specification for attaching a nucleic acid capture molecule to the disc is effective for any nucleic acid capture molecules regardless of their sequence. By analogy, just as the inventor of the Southern blot could satisfy the written description requirement for a claim to a nitrocellulose filter having a nucleic acid bound thereto without providing the sequences of all of the nucleic acids which

could potentially be bound to the filter because the methodology for binding the nucleic acid to the filter is independent of the sequence of the nucleic acid, the present inventors also satisfy the written description requirement for the pending claims because the methodology for attaching the claimed types of capture molecules to the CD described in the specification is independent of the sequence or structure of the capture molecules. The rule under MPEP 2163 is that:

> "The description need only describe in detail that which is new or not conventional. What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d at 1384, 231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.

The Specification, as was argued before, provides the GenBank Accession numbers of more than 40 genes. In the recent case decided by the US Court of Appeals for the Federal Circuit (*Falkner v. Inglis*, No. 05-1324, slip op. at 16-18 (Fed. Cir. 2006) (attached)) the Court clearly stated that: "However, it is the binding precedent of this court that Eli Lilly does not set forth a per se rule that whenever a claim limitation is directed to a macromolecule sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art." "Indeed, the forced recitation of known sequences in patent disclosures would only act as unnecessary bulk to the specification. Accordingly we hold that where <...> accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences, satisfaction of the written description requirement does not require either the recitation or incorporation by reference <...> of such genes and sequences." Additionally, as the Applicant argued previously, the EP 1 136 566 publication incorporated explicitly by reference in the Specification (page 7, lines 13-17) provides additional sequences of capture molecules (on pages 10, 11, 12, and 14). Altogether, the Specification provides written description of more than 60 sequences.

Therefore, a skilled artisan would have understood that the inventor was in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification. Thus, the adequate description requirement is met.

Enablement

The Examiner has maintained the rejection of claims 45, and 48-88 under 35 USC §112, first paragraph as allegedly non-enabled. Specifically, these claims were found allegedly non-enabled because: the nucleic acids immobilized on the surface of the disc were not described in the Specification as filed; and because "applicant's representative's argument have not shown where the state of the prior art was such that one would know how to immobilize said molecules, manufacture and use a device, be it handling, detecting, or reading device, where the support comprises said molecules, at the time of filing."

As discussed previously, the methodology disclosed in the specification for attaching a nucleic acid capture molecule to the disc is effective for any nucleic acid capture molecules regardless of their sequence. By analogy, just as the inventor of the Southern blot could satisfy the written description requirement for a claim to a nitrocellulose filter having a nucleic acid bound thereto without providing the sequences of all of the nucleic acids which could potentially be bound to the filter because the methodology for binding the nucleic acid to the filter is independent of the sequence of the nucleic acid, the present inventors also satisfy the written description requirement for the pending claims because the methodology for attaching the claimed types of capture molecules to the CD described in the specification is independent of the sequence or structure of the capture molecules. Furthermore, Figures 4 and 5 and paragraph [0071] provide enabling description of the disc where nucleic acids are located in a region of the disc that is void of any tracks or grooves. The same figures also show that the registered data from the CD track is read by one laser-based device, while the data from the array having nucleic acids is read by a separate reading device. During the course of the interview, the inventor had demonstrated a device for reading of a BioCD having the registered data on the bottom surface of the disc – as on the ordinary CD with pits and grooves, and the array located on the top surface of the disc. The reader was shown to have two reading devices: the bottom one was an ordinary CD-reading device for reading the registered data, while the top one was similar to OHP for reading the information from the array. The Examiner appreciated the presentation.

In addition, during the interview the Examiner noted that the claims recite that the claimed discs comprise "one or more nucleic acid capture molecules" bound thereto. According to the Examiner, the claims encompass discs with ESTs of no known utility bound thereto. As

suggested by the Examiner during the interview, Applicants note that the presence of inoperable embodiments within the scope of a claim does not necessarily render a claim non-enabled. M.P.E.P. §2164.08(b). Furthermore, " '[i]t is not a function of the claims to specifically exclude ... possible inoperative substances ...'" , unless the number of inoperative combinations becomes significant and requires a person having ordinary skill in the art to experiment unduly in order to practice the invention. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984) (quoting *In re Dinh-Nguyen*, 492 F.2d 856, 858-859 (CCPA 1974).

With respect to the present application, the specification enables one to make and use discs having a large number of useful nucleic acid capture probes bound thereto. In fact, because the methodology for binding the nucleic acid capture molecules to the disc is independent of the sequence of the capture molecules, the claimed invention can be utilized with countless numbers of useful sequences. Uncharacterized ESTs of no utility do not represent such a significant portion of the nucleic acid capture molecules encompassed by the claims to render the specification non-enabling, particularly in view of the fact that one skilled in the art would have no motivation to bind a useless nucleic acid capture molecule to the disc.

In addition, a claim is enabled so long as a person with skill in the art would be able to determine, without undue experimentation, which species within the scope of the claim would work and which would not. *In re Angstadt*, 537 F.2d 498, 503-05 (C.C.P.A. 1976). In the present situation, the manufacturer of the disc and the user of the disc know the identities of the nucleic acid capture molecules which are bound to the disc and the locations at which each of the nucleic acid capture molecules are bound. Thus, the manufacturers and users would know if any completely uncharacterized ESTs were fixed to the surface of the disc.

Finally, just as a description of a protocol for fixing a nucleic acid probe to nitrocellulose and hybridizing the fixed probe to a target nucleic acid enables one skilled in the art to perform a Southern blot even though uncharacterized ESTs are included among the many nucleic acids which could be fixed to the nitrocellulose using the Southern blot procedure, the description in the present specification of binding a nucleic acid capture molecule to a disc and hybridizing the capture molecule to a target nucleic acid enables one skilled in the art to make and use the claimed invention even though the one could use the procedures in the specification with uncharacterized ESTs.

For the foregoing reasons, Applicants respectfully request that the enablement rejection be withdrawn.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, arguments in support of the patentability of the pending claim set are presented above. In light of the above remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 27, 2006

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United States Court of Appeals for the Federal Circuit

05-1324
(Interference No. 105,187)

FALKO-GUNTER FALKNER, GEORG HOLZER, and FRIEDRICH DORNER,

Appellants,

v.

STEPHEN C. INGLIS, MICHAEL E.G. BOURSNELL, and ANTHONY C. MINSON,

Appellees.

John P. Isacson, Heller Ehrman LLP, of Washington, DC, argued for appellants. With him on the brief was Paul M. Booth.

Robert G. McMorrow, Jr., Connolly Bove Lodge & Hutz LLP, of Wilmington, Delaware, argued for appellee.

Appealed from: United States Patent and Trademark Office, Board of Patent Appeals and Interferences

United States Court of Appeals for the Federal Circuit

05-1324
(Interference No. 105,187)

FALKO-GUNTER FALKNER, GEORG HOLZER, and FRIEDRICH DORNER,

Appellants,

v.

STEPHEN C. INGLIS, MICHAEL E.G. BOURSNELL, and ANTHONY C. MINSON,

Appellees.

DECIDED: May 26, 2006

Before GAJARSA, Circuit Judge, ARCHER, Senior Circuit Judge and DYK, Circuit Judge.

GAJARSA, Circuit Judge.

This is an appeal from a decision of the Board of Patent Appeals and Interferences ("Board") in Interference No. 105,187, declared on December 24, 2003, between Falkner *et al.*, U.S. Patent No. 5,770,212 ("the Falkner '212 patent") and Inglis *et al.*, U.S. Application Serial No. 08/459,040 ("the Inglis '040 application"). The Administrative Patent Judge (APJ) designated Inglis as the senior party. On December 29, 2004, the Board issued a final decision, holding that Falkner could not antedate Inglis' September 25, 1990 priority date, and entered judgment against Falkner on the

sole count of the interference. It ordered that Falkner was not entitled to claims 1-19 of the Falkner '212 patent. It further ordered that Inglis was entitled to claims 9, 10, 29 and 30 of the '040 application. Falkner filed a timely notice of appeal. This Court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. §§ 141 and 142. For the reasons discussed below, we affirm the judgment of the Board.

I. BACKGROUND

A. The Invention

Some vaccines against a virus (the "target virus") incorporate harmless fragments of the target virus's genetic material into a second virus, called a "viral vector." When a person is vaccinated, the viral vector produces harmless fragments of the target virus, ultimately conferring immunity against it. To prevent the viral vector from itself causing a harmful infection in the inoculee, it must be attenuated. Attenuation is achieved by deleting or inactivating one or more genes responsible for the vector's growth and infectiousness. However, because the vaccine is produced by essentially "growing" the vector virus (accompanied by its inserted target virus gene), attenuation makes it difficult to manufacture the vaccine. The traditional solution to this problem has been to inactivate genes known as "inessential" genes. With inessential genes inactivated, the viral vector is substantially less pathogenic. At the same time, because the vector virus can still fully reproduce itself, albeit more slowly, the vaccine can be produced in commercial quantities. However, the traditional approach carried a disadvantage, namely the risk that the vector virus, though attenuated, could still cause a harmful infection in the inoculee.

The inventors discovered a way of making vaccines safer by deleting or inactivating an essential, rather than an inessential, gene from the viral vector's genome, while at the same time solving the production problem by growing the vaccines in cells that were complementarily modified to produce the absent essential viral gene product "on behalf of" the vector virus. Thus, the modified vector virus could be readily grown in these complementarily-modified cells, but not in other cells, such as those of an inoculee.

This approach is applicable to many different kinds of vector viruses, e.g., adenoviruses, herpesviruses, poxviruses and retroviruses. The subject matter of this interference, however, is directed specifically to vaccines in which the vector virus is a poxvirus. For many vector viruses, there is a risk that vectors that have been attenuated in essential genes can "swap" genes with the host cell genome, thereby reacquiring their deleted genes and reverting to wild-type virus. This risk can be minimized through the use of viruses that are "cytoplasmic", meaning that they are unlikely to enter the cell nucleus. Because a cell's genes are located in the nucleus, cytoplasmic viruses such as poxvirus cannot swap genes with the cell genome and possibly revert to a virulent wild-type virus.

B. Defining the Count and Assigning Priority

The sole count of the interference was either "[a] vaccine according to Claim 1 of Falkner's 5,770,212 patent or a vaccine according to Claim 29 of Inglis' 08/459,040 application." Claim 29 of the Inglis '040 application reads:

> A vaccine comprising a pharmaceutically acceptable excipient and an effective immunizing amount of a mutant virus, wherein said mutant virus is a mutant poxvirus and has a genome which has an inactivating mutation in a viral gene, said viral gene being essential for the production of

> infectious new virus particles, wherein said mutant virus is able to cause production of infectious new virus particles in a complementing host cell gene expressing a gene which complements said essential viral gene, but is unable to cause production of infectious new virus particles when said mutant virus infects a host cell other than a complementing host cell; for prophylactic or therapeutic use in generating an immune response in a subject.

(emphasis added)

Claim 1 of the Falkner '212 patent reads:

> A vaccine comprising (a) a defective poxvirus that lacks a function imparted by an essential region of its parental poxvirus, wherein (i) said defective poxvirus comprises a DNA polynucleotide encoding an antigen and said DNA polynucleotide is under transcriptional control of a promoter, and (ii) the function can be complemented by a complementing source; and (b) a pharmaceutically acceptable carrier.

The Administrative Patent Judge (APJ) designated claims 1-19 of the Falkner '212 patent and claims 9,10, 29, and 30 of the Inglis '040 application as corresponding to the interference count.[1] Both parties sought the benefit of earlier-filed applications to establish dates of constructive reduction to practice.[2] The ALJ accorded the Inglis '040

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[1] Inglis's claim 29 is his broadest claim, directed to poxvirus; and claim 30, which depends on claim 29, is a poxvirus vaccine for mammalian subjects. Claim 9 is directed to poxvirus but contains some additional limitations unrelated to the type of virus used; claim 10 depends on claim 9 and is directed to a single species of poxvirus, namely vaccinia virus. Falkner's claims 2-10 depend on claim 1. Falkner claim 10 is directed to a method of producing the vaccine of claim 1, and the remaining method claims depend thereon.

[2] Priority in an interference goes to the first to invent, but a rebuttable presumption exists that the inventors made their inventions in the chronological order of their effective filing dates, namely that the senior party invented first, see 37 C.F.R. § 1.657(a) (2004), and the junior party bears the burden of proving otherwise, see § 1.657(b), such as by proving that she actually reduced the invention to practice before the constructive filing date (priority date) of the senior party, or that she was first to conceive and diligently reduced the invention to practice, starting from a date prior to reduction to practice by the senior party. See 35 U.S.C. § 112(g) (2000). Falkner sought to rely, in part, on an alleged date of conception and beginning of reasonable diligence: April 27, 1994.

application (filed June 2, 1995) the benefit of several earlier-filed applications, dating back to September 25, 1990.[3] Likewise, the APJ accorded the Falkner '212 patent (issued June 23, 1998 from an application filed February 21, 1997) the benefit of earlier-filed applications, but these dated back only to April 29, 1994.[4] Consequently, the APJ designated Inglis as the senior party.

C. Board Decision

The specifications of all of Inglis' earlier applications were similar. Although they focused on herpesvirus vectors, they contained several passages related to poxvirus-based vaccines. Because Falkner believed that these passages did not adequately describe and enable the poxvirus invention, he challenged both Inglis' entitlement to priority as to the count and the patentability of Inglis' corresponding claims. Falkner brought these challenges in three closely-related preliminary motions before the Board.

On September 13, 2004, the "600" rules expired in favor of new rules found at 37 C.F.R. § 41.100 et seq. However, the Board correctly chose to decide the matter under the old rules, given the parties' reliance on them in filing all motions, oppositions, and replies in the case, which were completed before the new rules took effect. See Singh v. Brake, 222 F.3d 1362, 1371 (Fed. Cir. 2000) (applying a new procedural rule if and only if it did not affect the parties' reliance interests).

[3] The Inglis priority applications were U.S. Application Serial No. 08/384,963 ("the Inglis '963 application"), filed February 7, 1995; U.S. Application Serial No. 08/030,073 ("the Inglis '073 application"), filed May 20, 1993; WO/92/05263, PCT/GB91/01632 ("the Inglis PCT application"), filed September 23, 1991, published in English on April 2, 1992; GB 9104903.1 ("the Inglis 1991 British application"); filed March 8, 1991; and GB 9020799.4 ("the Inglis 1990 British application"), filed September 25, 1990. The Inglis '040 application is a continuation in part of the '963 application, which was in turn a continuation of the Inglis '073 application. The '073 application corresponded to the Inglis PCT application. The Inglis PCT application claimed priority to, and was essentially identical to, the Inglis 1990 and 1991 British applications.

[4] The Falkner priority applications were U.S. Application Serial No. 08/616,313 ("the Falkner '313 application") filed March 14, 1996; and U.S. application Serial No. 08/235,392 ("the Faulkner '392 application"), filed April 29, 1994.

In each, as the moving party, Falkner carried the burden of proof by a preponderance of the evidence. See 37 C.F.R. § 1.637(a); see also Kubota v. Shibuya, 999 F.2d 517, 520 n.2 (Fed. Cir. 1993) (explaining that "[t]he term 'burden of proof' . . . means the burden to establish the proposition at issue by a preponderance of the evidence").

Falkner brought his first preliminary motion pursuant to 37 C.F.R. § 1.633(a),[5] arguing that the claims in Inglis's involved ('040) application that corresponded to the count were unpatentable because they failed to meet the written description requirement of 35 U.S.C. § 112. In support of his argument, he stated, inter alia, that (1) the specification of Inglis's '040 application did not identify any essential genes in poxvirus or describe the inactivation of such genes, (2) vaccines based on vaccinia (a type of poxvirus) had not yet been produced, and (3) the bulk of the Inglis specification was directed not to poxviruses but to herpesviruses. The Board denied Falkner's motion, based in part on his failure to address the perceived shortcomings of the '040 claims in light of the specification.

Second, Falkner moved pursuant to 37 C.F.R. §§ 1.633(g) & 1.637(g) to deny Inglis the priority benefit of his earlier applications, arguing that they did not sufficiently

[5] On September 13, 2004, the "600" rules expired in favor of new rules found at 37 C.F.R. § 41.100 et seq. However, the Board correctly decided the matter under the old rules, given the parties' reliance on them in filing all motions, oppositions, and replies in the case, which were completed before the new rules took effect. See Singh v. Brake, 222 F.3d 1362, 1371 (Fed. Cir. 2000) (applying a new procedural rule if and only if it did not affect the parties' reliance interests); see also Brown v. Barbacid, 436 F.3d 1376, 1379 n.1 (Fed. Cir. 2006) (holding that the Board did not err in applying the old rules "under which this case was decided").

describe and enable the claims in question.[6] Falkner argued that without the benefit of these applications Inglis would be unable to establish constructive reduction to practice earlier than Falkner. Falkner would win priority as to the count, and Inglis' corresponding claims would be unpatentable. In support of his motion, Falkner alleged deficiencies in Inglis' benefit specifications similar to those raised in his first motion. The Board carefully articulated the legal standard, correctly explaining that "benefit with respect to priority in an interference is granted with respect to counts not claims" and that "[a]ll that is necessary for a party to be entitled to benefit of an earlier filed application for priority purposes is compliance with 35 U.S.C. § 112 with respect to at least one embodiment within the scope of the count." Board Op. at 7 (citing Hunt v. Treppschuh, 523 F.2d 1386, 1389 (CCPA 1975) (holding that where a "parent application is relied upon as a prior constructive reduction to practice[,] . . . . the § 112, first paragraph requirements need only be met for an embodiment within the count")). After careful review of the record, the Board held that Falkner had failed to meet his burden of proof.

Third, Falkner moved for judgment pursuant to 37 C.F.R. § 1.633(a) that the claims in Inglis' involved ('040) application that corresponded to the count were anticipated and therefore unpatentable. He argued that because Inglis' earlier applications had failed to adequately describe and enable the full scope of his current claims, the current claims could not be accorded the benefit of 35 U.S.C. § 120 for the

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[6] Falkner did not argue lack of enablement with respect to the Inglis '963 patent because he believed that the teachings of the Falkner '392 patent, filed in 1994, would have enabled the subsequent '963 patent.

purpose of antedating patent-defeating prior art.[7] The Board explained that 35 U.S.C. §§ 119 & 120 require benefit applications to comply with § 112, first paragraph, with respect to the full scope of what a party now claims, rather than with respect to merely one embodiment within the scope of the interference count. After carefully considering the written description and enablement issues, the Board denied the motion. As a result of the denial of Falkner's several motions, Inglis remained the senior party, and the Board ordered judgment as to the subject matter of the count in favor of Inglis.

D. Issue and Standard of Review

On appeal, Falkner essentially reiterates the arguments that he made before the Board. While we recognize that each of these three arguments is distinct, they are nonetheless all related, and under the facts of this particular case, we need only to resolve the following common issue: whether the Inglis benefit applications adequately describe and enable a poxvirus-based vaccine. Falkner also argues that the Board committed other errors, such as initially designating Inglis as the senior party and failing to afford Falkner an opportunity for briefing prior to making this designation. These arguments lack merit, and we shall not further discuss them. We turn, therefore, to the central issues in this case: written description and enablement.

Written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date. See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Enablement is a question of law involving underlying factual inquiries. See Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361,

[7] Here, Falkner points to his own U.S. Pat. No. 5,766,882 ("the '882 patent'), issued in March 1995, as the patent-defeating prior art.

1365 (Fed. Cir. 1997); see also In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (holding that whether undue experimentation is required is a "conclusion reached by weighing many factual considerations. . . . includ[ing] (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.").

This court applies the standards of the Administrative Procedure Act ("APA") in reviewing decisions of the Board. See Dickinson v. Zurko, 527 U.S. 150, 152 (1999) (holding that 5 U.S.C. § 706 governs our review of PTO appeals). Accordingly, we will set aside actions of the Board if they are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, and we set aside factual findings that are unsupported by substantial evidence. See In re McDaniel, 293 F.3d 1379, 1382 (Fed. Cir. 2002) (citing 5 U.S.C. § 706); see also In re Sullivan, 362 F.3d 1324, 1326 (Fed. Cir. 2004) (substantial evidence review of factual findings). We review questions of law de novo. See Rapoport v. Dement, 254 F.3d 1053, 1058 (Fed. Cir. 2001).

Substantial evidence is defined as that which a reasonable person might accept as adequate to support a conclusion. See In re Zurko, 258 F.3d 1379, 1384 (Fed. Cir. 2001). It requires an examination of the record as a whole, taking into account both the evidence that justifies and detracts from an agency's opinion. See In re Gartside, 203 F.3d 1305, 1312 (Fed. Cir. 2000). An agency decision can be supported by substantial evidence, even where the record will support several reasonable but contradictory conclusions. See id.; see also In re Jolley, 308 F.3d 1317, 1320 (Fed. Cir. 2002).

II. DISCUSSION

A. Contents of the Inglis Priority Applications

The claims that correspond to the count of the interference are directed to a novel type of vaccine that is comprised of a "vector virus" in the poxvirus family. Conceptually, poxviruses are a "subgenus" of viruses that includes the "species" vaccinia. All of the prior Falkner applications described poxvirus vaccine vectors in detail, and to the exclusion of other types of vaccine vectors (e.g., herpesvirus vaccine vectors). These applications provided five detailed working examples regarding the preparation and use of vaccines from defective poxviruses. They also described the use of a particular species of poxvirus vaccine vector, namely vaccinia virus.

In contrast, the Inglis applications described vaccine vectors in general, and then focused on the subgenus of herpesviruses, for which they provided a detailed example. Nevertheless, at least three passages discussed the poxvirus invention and specifically mentioned "vaccinia virus."[8] For example, after introducing the concept of vaccine vectors, the specification states that "[t]ypically members of the pox virus family, e.g. vaccinia virus, are used as vaccine vectors."[9] The specification later discusses the deletion of essential genes from vaccine vector genomes, noting that the "invention can

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[8] We recognize that the Inglis applications do not describe any actual reduction to practice of a poxvirus vaccine. See Carroll Declaration (stating that the '040 application did not contain any discussion of the "actual creation of the recited 'mutant poxvirus'" and that the application in fact stated "that a vaccinia virus with a deletion in an essential gene had not been produced."). As we discuss below, however, an actual reduction to practice is unnecessary to satisfy the written description requirement.

[9] Because of the substantial similarity in the specifications of all of the Inglis benefit applications, we shall refer in this opinion to representative passages from the earliest of the applications, the Inglis 1990 British application.

be applied to any virus where one or more essential gene(s) can be identified and deleted from or inactivated within the virus genome" (emphasis added). Moreover, it provides that "the virus may comprise an orthopox virus, for example, vaccinia virus, which may comprise a heterologous sequence encoding an immunogen derived from a pathogen." Finally, it reads:

> For example vaccinia virus, a poxvirus, can carry and express genes from various pathogens, and it has been demonstrated that these form effective vaccines when used in animal experimental systems. The potential for use in humans is vast, but because of the known side effects associated with the widespread use of vaccinia as a vaccine against smallpox, there is reluctance to use an unmodified vaccine in humans. There have been attempts to attenuate vaccinia virus by deleting non-essential genes such as the vaccinia growth factor gene. . . However, such attenuated viruses can still replicate in vivo, albeit at a reduced level. No vaccinia virus with a deletion in an essential gene has yet been produced, but such a virus, deleted in an essential gene as described above, with its complementing cell for growth, would provide a safer version of this vaccine.

The application provides a detailed example of an embodiment that comprised not a poxvirus, but a herpesvirus, including the identity of the deleted essential sequences therein. Nevertheless, for the reasons discussed below, we find no error in the Board's determinations on the adequacy of written description and enablement in the various Inglis disclosures.

B. Enablement

Because the adequacy of the disclosure is judged from the perspective of one of ordinary skill in the art, we start our review of the Board's decision by noting that the parties stipulated to a high level of skill in the art. They defined the skilled artisan as having 5-10 years experience creating recombinant poxvirus, as being familiar with the poxvirus literature, the use of poxvirus as a vector for the expression of heterologous genes, and having the "needed technical skill to practice the experimentation described

in the scientific literature relating to recombinant virus, including poxvirus." The Board agreed with the parties' stipulation as to level of skill.

The Board did not err in finding Inglis' claims to be enabled as a matter of law, in light of its articulated underlying factual findings. In support of its conclusion, it noted that "there is extensive disclosure of the selection of an essential gene, its deletion or inactivation and the production of a mutated virus with said deleted or inactivated gene, albeit for herpesvirus." Moreover, because the differences between the herpesviruses and poxviruses were well known, this would have aided the person of ordinary skill in the art in her application of the lessons of the herpesvirus example in the construction of poxvirus vaccines. The Board observed that "the mere fact that the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be 'undue' in this art. Indeed, great expenditures of time and effort were ordinary in the field of vaccine preparation." Thus, the Board found the Inglis applications to be enabling.

Reviewing the Board's legal conclusion of enablement, as based on its underlying findings of fact, we cannot say that the Board erred. With respect to a skilled artisan's ability to identify "essential" poxvirus genes, as discussed below we note that there was undisputed testimony that as of the time of filing of the earliest Inglis application publications in professional journals had disclosed the DNA sequence of the poxvirus genome along with the locations of the "essential regions." The person of ordinary skill in the art would clearly have possessed such knowledge, and given the ready accessibility of the journals, the absence of incorporation by reference is not problematic. Indeed, "[a] patent need not teach, and preferably omits, what is well

known in the art." Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1534 (Fed. Cir. 1987).

C. Written Description

On appeal to this court, Falkner essentially reargues the positions on written description that he took before the Board. Although the Board erred in its articulation of the written description standard, that error is harmless. The Board held that "an actual possession standard is not required." (emphasis added). But our precedent clearly establishes that "[t]he applicant must . . . convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Nonetheless, we conclude there is no need for remand because the undisputed testimony supports the Board's ultimate conclusion.

As noted above, the Board found several passages in the Inglis '040 application (and in the benefit applications) that were directed to poxvirus. No length requirement exists for a disclosure to adequately describe an invention. See In re Hayes Microcomputer Prods., Inc. Patent Litig., 982 F.2d 1527, 1534 (Fed. Cir. 1992) ("[T]he adequacy of the description of an invention depends on its content in relation to the particular invention, not its length."). Furthermore, the testimony of Falkner's expert, Dr. Boursnell, established that the articles describing essential genes for poxvirus were well-known in the art. Dr. Boursnell testified that "the skilled person would have been readily able to choose an essential vaccinia gene" based on references that have been publicly available since 1990. The testimony of Inglis' expert, Dr. Carroll, did not refute this claim.

The parties also dispute several aspects of our law of written description, which we now address. We conclude that the Board applied correct law. Specifically, we hold, in accordance with our prior case law, that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.

1. Examples Are Not Required

First, it is clear that the absence of examples involving poxviruses in the Inglis applications does not render the written description inadequate. As we explained in LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc.:

> A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation.

424 F.3d 1336, 1345 (Fed. Cir. 2005) (citing Union Oil Co. v. Atl. Richfield Co., 208 F.3d 989, 997 (Fed. Cir. 2000); In re GPAC Inc., 57 F.3d 1573, 1579 (Fed. Cir. 1995)).

2. Actual Reduction to Practice Is Not Required

As we explained in Capon v. Eshhar, "[t]he 'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the

patentee was in possession of the invention that is claimed." 418 F.3d 1349, 1357 (Fed. Cir. 2005). The Board was correct, however, not to view as dispositive that Inglis had not actually produced a poxvirus vaccine,[10] because an actual reduction to practice is not required for written description.[11] See Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 926 (Fed. Cir. 2004) ("We of course do not mean to suggest that the written description requirement can be satisfied only by providing a description of an actual reduction to practice. Constructive reduction to practice is an established method of disclosure . . . ."). Rochester, moreover, is consistent with Supreme Court precedent. In the context of interpreting 35 U.S.C. § 102(b), the Court held that "[t]he word 'invention' must refer to a concept that is complete, rather than merely one that is 'substantially complete.'" Pfaff v. Wells Elecs., 525 U.S. 55, 66 (1998). It then proceeded to make clear that although "reduction to practice ordinarily provides the best evidence that an invention is complete. . . . it does not follow that proof of reduction

[10] The Inglis specifications stated that "[n]o vaccinia virus with a deletion in an essential gene has yet been produced, but such a virus, deleted in an essential gene as described above, with its complementing cell for growth, would provide a safer version of this vaccine."

[11] The Board believed that Falkner's expert, Dr. Carroll, had premised his opinions on the misunderstanding that actual reduction to practice was required to prove written description, and it discredited his expert opinion.

to practice is necessary in every case." Id. (emphasis added).[12] Thus, to the extent that written description requires a showing of "possession of the invention," Capon, 418 F.3d at 1357 (emphasis added), Pfaff makes clear that an invention can be "complete" even where an actual reduction to practice is absent.[13] The logical predicate of "possession" is, of course, "completeness."

3. Recitation of Known Structure Is Not Required

Falkner argues, inter alia, that the Inglis specifications do not adequately describe the poxvirus invention, in light of Eli Lilly, because they do not describe the "essential regions" of any poxvirus. 119 F.3d 1559. We note, in addition, that Inglis did not attempt to incorporate by reference any literature that described the DNA sequence of the poxvirus genome and the locations of the "essential regions." However, it is the binding precedent of this court that Eli Lilly does not set forth a per se rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art. See Capon, 418 F.3d at 1357 ("None of the cases to which the Board attributes the requirement of total DNA re-analysis, i.e., Regents v. Lilly, Fiers v. Revel, Amgen, or

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[12] Similarly, this court has carefully explained the relationship between written description and possession, explaining that a showing of possession is not necessarily sufficient to demonstrate the adequacy of written description. See, e.g., Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1330 (Fed. Cir. 2002) ("[P]roof of a reduction to practice, absent an adequate description in the specification of what is reduced to practice, does not serve to describe or identify the invention for purposes of § 112, P 1. As with 'possession,' proof of a reduction to practice may show priority of invention or allow one to antedate a reference, but it does not by itself provide a written description in the patent specification.").

[13] In contrast to reduction to practice, conception is a prerequisite to an adequate written description. See Fiers v. Sugano, 984 F.2d 1164, 1171 (Fed. Cir. 1993) ("[O]ne cannot describe what one has not conceived.").

Enzo Biochem, require a re-description of what was already known."). Thus, "[w]hen the prior art includes the nucleotide information, precedent does not set a per se rule that the information must be determined afresh." Id. at 1358. Rather, we explained that:

> The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.

Id. at 1357.

Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention. As we stated in Capon, "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." Id. at 1358. Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification. Accordingly we hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written description requirement does not

require either the recitation or incorporation by reference[14] (where permitted) of such genes and sequences.

In conclusion, having reviewed the decision of the Board, we can discern no error in its conclusion that the disclosures relied upon by Inglis for priority purposes adequately described and enabled the invention directed to poxvirus, there being substantial evidence to support these findings. Consequently, we hold that the Board's award of priority to Inglis was proper.

AFFIRMED

No costs.

[14] Here, the patentee did not attempt incorporation by reference. Where, of course, certain material that is not present in the specification is deemed nonessential to the satisfaction of the written description requirement, the issue of proper incorporation by reference vel non is irrelevant.